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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,239	04/30/2002	William Webster Thompson	X-12636	2652

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ELI LILLY AND COMPANY
PATENT DIVISION
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INDIANAPOLIS, IN 46206-6288

EXAMINER

FONDA, KATHLEEN KAHLER

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/15/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,239

Applicant(s)

THOMPSON ET AL.

Examiner

Kathleen Kahler Fonda, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7-12-02, 12-13-02, & 1-14-03 (IDS forms).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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If priority as recited in the inventors' declaration is desired, Applicant should amend the specification to include the priority data as the first paragraph after the title.

Applicant is requested to provide a copy of the abstract which is by itself on a separate sheet which does not contain additional information.

Applicant is advised that no references were received with the Information Disclosure Statement of 07-12-02. However, documents BA, BH, BI, and CB were among the documents transmitted by the International Bureau, and the remaining U.S. a foreign patents documents were available to the Examiner electronically. Thus all patent documents, as well as reference CB, have been reviewed; the remaining documents cited on the IDS of 07-12-02 have not.

If Applicant chooses to submit the missing documents, Applicant should note that the IDS reference to document CC does not include a date. Applicant is advised that at least the year must be provided if Applicant wishes the reference to be listed on the face of any patent which may eventually issue from this application.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over BOECK *et al.* (AH) in view of BURTON *et al.* (CBB).

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Applicant claims a formulation comprising an ectoparasiticial amount of spinosyn or a physiologically acceptable derivative or salt thereof milled to an average particle size of from about 1 to about 15 microns; a surfactant effective to facilitate wetting; a dispersant such that the ratio of spinosyn to dispersant is from about 3:1 to about 1:5; and water. Applicant also claims an article of manufacture comprising a unit dose of the formulation, packaging, and instructions. Applicant claims a method of making the formulation comprising wet-milling to size, blending with a mineral thickener, and diluting. Finally, Applicant claims a methods of controlling an ectoparasite infestation by administering the formulation to an animal. Dependent claims further limit particle size, relative amounts, and the nature of particular ingredients.

BOECK teaches compounds A83543A and A83543D, which correspond respectively to spinosyn A and spinosyn D; see the abstract and columns 3-4. The compounds are active as ectoparasiticides; see the section beginning at the bottom of column 26. BOECK also teaches formulations which comprise spinosyns, surfactants, dispersants such as silica or naphthalenesulfonate salt; antifoam agents; xanthan; and water. See Examples 12A and 13C in particular. BOECK teaches water

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dispersible granules comprising spinosyn and a dispersant wherein the concentration of spinosyn is about 10-90% by weight; see column 25, lines 21-25. The aqueous suspensions of BOECK may comprise 5-50% by weight of spinosyn; see column 25, lines 51-54. Various surfactants and inert ingredients may be used to promote emulsification and to optimize density and viscosity; see column 25, lines 28-39 and 54-60. The active ingredient may be milled to decrease particle size; see column 25, lines 60-63. BOECK teaches topical application of the suspension to animals to achieve control of ectoparasites, and that formulations comprising 0.00005 to 5.0% of the active ingredient are effective; see column 31, lines 56-61.

BOECK does not specifically disclose spinosyn having a particle size of from about 1 to about 15 microns, and does not specifically exemplify each of the limitations of the dependent claims as to particle size, relative amounts, and the nature of particular ingredients.

Figure 1 of BURTON shows spinosyns A and D, which are the active ingredients in Tracer[®] (see the last full sentence in the left column of page 871 of THOMPSON et al. (CCC)). BURTON teaches a controlled particle size of between 2 and 6 microns, and that such particle size provides a formulation which "will suspend very well." See page 696, right column, lines 1-3. The

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BURTON formulation is aqueous, and is useful as an insecticide. See the abstract.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to choose a particle size of from about 1 to about 15 microns. A worker of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, because BURTON had taught that a particle size of about 2-6 microns allowed for effective suspension of the active ingredient. The claimed article of manufacture would have been obvious over the cited references for the purpose of convenience for the end-user of the ectoparasiticide formulation. The steps of claim 11 would have been obvious because BOECK suggests milling and BURTON teaches the appropriate particle size, and one ordinarily skilled in the art would recognize that blending and diluting as claimed would be necessary to achieve aqueous suspensions such as those in Examples 12A and 13C of BOECK. The relative amounts and limitations on the nature of particular ingredients as claimed are within the scope of the general teaching of BOECK and BURTON, even if not specifically exemplified, so the claims are considered obvious absent any evidence of unexpected results.

No claim is allowed.

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Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be

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directed to the Technology Center 1600 receptionist whose
telephone number is (703) 308-1235.



Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
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